UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, Defendants.	No. 25-CV-00849-EP-JRA

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR A STAY OF INJUNCTION PENDING APPEAL

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Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and Novadoz Pharmaceuticals LLC (collectively, "MSN"), respectfully submit this memorandum of law in support of its Motion to Stay the Court's Preliminary Injunction pending appeal.

PRELIMINARY STATEMENT

A stay pending appeal is needed to preserve meaningful appellate review of the Court's preliminary injunction order (the "Order") barring MSN from releasing an FDA-approved generic version of Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation's (collectively, "Novartis") Entresto heart medication. The Court's Order rests on a series of manifest legal errors: it misapprehends the standard and the evidence necessary to demonstrate irreparable harm; it fails to balance the four preliminary injunction factors; and it misstates and misapplies substantive trade dress law to protect tablet shapes and colors that are functional and commonplace. The Order will wreak irrevocable harm on MSN, wiping out years of MSN's product development and regulatory efforts, and deprive the public of a much needed, lower cost alternative to critical medication. The factors for a stay of an injunction strongly weigh in favor of MSN.

First, MSN is likely to prevail on the merits of its appeal. Novartis failed to make the showing of irreparable harm required for a preliminary injunction. Novartis's sole asserted injury was an entirely speculative, evidence-free theory of

reputational harm based on the fanciful notion that (1) a doctor could write a prescription for sacubitril/valsartan and fail to start patients on the correct initial dosing regimen—even though the doctor is already familiar with Entresto's label, (2) a patient could be harmed by imaginary defects in MSN's drug or due to MSN's drug label even though the U.S. Food and Drug Administration ("FDA") and other courts have already considered and rejected those very arguments; (3) the doctor would confuse the parties' drugs based solely on their physical appearance, ignoring their different brand names, even though he does not lay eyes on the drugs when filling out the prescription; and (4) this confusion would cause the doctor to blame Novartis for the conjectured flaws in MSN's drug. And all this would have to happen between the time of the Court's ruling on a preliminary injunction and the anticipated final judgment, thus necessitating preliminary injunctive relief to preserve the purported status quo. The Court made no evidentiary findings supporting this supposed hypothetical scenario. Indeed, it made the express contradictory finding that both doctors and patients are fully aware of and discuss generic substitution, thereby eliminating any chance of real-world confusion in the first instance. As a matter of law, such a speculative risk of harm, unmoored from evidence, cannot support the drastic remedy of a preliminary injunction.

Novartis also failed to show a likelihood of success on the merits of its claims. The Court's conclusion that Novartis's trade dress was nonfunctional directly

contravened governing Third Circuit precedent: instead of asking whether the trade dress was "useful," the Court impermissibly found against MSN because it purportedly had "alternatives." *Ezaki Glico Kabushiki Kaisha v. Lotte Int'l Am. Corp.*, 986 F.3d 250, 256, 260 (3d Cir. 2021). And the Court's determination that Novartis's trade dress had achieved secondary meaning was based on a clear misapplication of the relevant factors and ignored overwhelming evidence that Novartis's trade dress consists only of commonly used, and thus unprotectable, shape-and-color combinations.

Second, the irreparable harm to MSN if a stay is not granted is beyond dispute. As the Court found, "[t]here is no question that MSN would suffer significant hardship if enjoined. . . . It would lose 'first mover advantage' and face financial, research and development setbacks." ECF 32 ("Op.") at 18. With MSN poised to launch its product imminently, a preliminary injunction causing a delay of even a few weeks while MSN takes an emergency appeal to the Third Circuit could cost MSN the ability to be the first to launch in the market, with ruinous economic and reputational consequences.

Third, balancing the harms strongly favors a stay. Novartis has offered no evidence of actual harm—simply a *theory* of reputational damage that stands in stark contrast to the Court's findings of harm to MSN. If a stay were granted, there would be no harm to Novartis not compensable in monetary damages. And the Court can

and should obviate any risk of harm to Novartis by setting this case for an expedited trial.

Finally, the public interest stakes of this case are uniquely high. The Court's expansive injunction grants Novartis exclusive rights to prevent any use of purple, yellow, and pink oval-shaped tablets for a generic version of Entresto. Thus, the Court's reasoning could give Novartis the ability to challenge the launch not only of MSN's drug but also those of *every other generic Entresto manufacturer*, since they all appear to have followed the same FDA guidance and functional concerns as MSN in choosing their pills' shapes and colors. Novartis would be allowed to extend its patent monopoly well past its expiration date, the public would be deprived of affordable versions of a life-saving medication, and FDA guidance and industry practice for generic drugs would be upended.

Though MSN should ultimately prevail in this lawsuit, at a minimum, the questions are sufficiently close and serious to warrant a stay while MSN seeks an appellate ruling on these important issues.

PROCEDURAL HISTORY

As the latest step in a years-long battle to prevent MSN from launching its generic Entresto drug, Novartis sued MSN for trade dress and trademark infringement and moved for a preliminary injunction (the "Motion"). ECF 1; ECF 4-1. In its Motion, Novartis claimed trade dress rights in the designs of its Entresto

drug—specifically the size, shape, and color of the three doses of Entresto, both individually and as a three-dose trio. ECF 4-1 ("PI Mot."). On March 17, 2025, the Court issued a decision denying the Motion as to Plaintiffs' trademark infringement claims but granting it as to Plaintiffs' trade dress infringement claim. Op. The Court preliminarily enjoined MSN "from manufacturing, producing, distributing, circulating, selling, marketing, offering for sale, advertising, promoting or displaying [] MSN's [generic Entresto d]rug, in a manner likely to infringe on Plaintiffs' trade dress." ECF 33.

LEGAL STANDARD

A district court may "suspend or modify" an injunction during the pendency of an appeal from an interlocutory order. Fed. R. Civ. P. 62(d). A stay pending appeal will be granted when the movant has shown (1) a likelihood of success on the merits, (2) irreparable injury absent a stay; (3) that issuance of the stay will not substantially injure the other parties interested in the proceeding; and (4) that the public interest favors a stay. *Nken v. Holder*, 556 U.S. 418, 434 (2009). Critically, the factors are evaluated on a sliding scale, so that a strong showing in one factor excuses a weaker showing in another. *In re Revel AC, Inc.*, 802 F.3d 558, 570–71 (3d Cir. 2015). MSN meets all of these factors.

ARGUMENT

I. THE COURT SHOULD ISSUE A STAY PENDING APPEAL.

A. MSN Is Likely to Succeed on the Merits of Its Appeal.

MSN is likely to succeed in overturning the preliminary injunction on appeal. Under the first *Nken* factor, MSN need *not* show that it is "more likely than not" to prevail on its appeal. *Revel AC*, 802 F.3d at 569 (quoting *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc)). It need only show "a reasonable chance, or probability," of prevailing. *Id.* at 568 (quoting *Singer*, 650 F.3d at 229). MSN readily meets that standard.

The Third Circuit recently reemphasized that a preliminary injunction is an "extraordinary remedy that should be granted only in limited circumstances." *Delaware State Sportsmen's Ass'n, Inc. v. Delaware Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 200 (3d Cir. 2024) (brackets omitted) (quoting *Mallet & Co. v. Lacayo*, 16 F.4th 364, 391 (3d Cir. 2021)), *cert. denied sub nom. Gray v. Jennings*, 2025 WL 76443 (U.S. Jan. 13, 2025). Courts must use "extreme caution" in considering requests for a preliminary injunction, *id.* at 199, and "reserve this drastic remedy for drastic circumstances." *Id.* at 206.

To obtain a preliminary injunction, Novartis was required make "*a clear showing*" that (1) it was likely to succeed on the merits, (2) it was likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tipped in its favor, and (4) the public interest favored such relief. *Id.* at 202

(emphasis in original). Novartis was required to make that clear showing *for each factor*. *See Nichino Am., Inc. v. Valent U.S.A. LLC*, 44 F.4th 180, 187 (3d Cir. 2022) ("[A] plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate.").

As an initial matter, the Court failed to apply the relevant standard. The Court discussed likelihood of success and irreparable harm, but did not engage in any balancing of the relative harms to the parties and did not make a finding on the public interest factor at all. As explained below, the Court's own factual findings compel the conclusion that the third and fourth preliminary injunction factors favored MSN. That alone was sufficient to deny Novartis's motion: "the Supreme Court has overturned an injunction based solely on the balance of equities and the public interest." *Delaware State*, 108 F.4th at 202 (citing *Winter v. NRDC*, 555 U.S. 7, 26, 32 (2008)).

In any event, as explained below, each of the preliminary injunction factors plainly favored MSN.

1. Novartis Never Demonstrated Irreparable Harm.

Novartis needed to show that, "without a preliminary injunction, [it] will more likely than not suffer irreparable injury *while proceedings are pending*." *Delaware State*, 108 F.4th at 204 (emphasis added). In other words, Novartis needed to demonstrate "that without a preliminary injunction, the District Court will be unable

to decide the case or give them meaningful relief." *Id.* at 205. "[I]rreparable harm must be likely, not merely possible." *Buzz Bee Toys, Inc. v. Swimways Corp.*, 20 F. Supp. 3d 483, 511 (D.N.J. 2014). A "generalized claim of harm is hardly enough to call for [the] 'extraordinary and drastic remedy'" of a preliminary injunction. *Delaware State*, 108 F.4th at 205 (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997)). Novartis came nowhere near satisfying this standard.

a. The Court Applied the Wrong Legal Framework to Assess Irreparable Harm.

The Court's analysis of irreparable harm entirely misconstrued the burden-shifting framework for proving irreparable harm in trademark cases. *See* Op. at 17.

First, the Court cited *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 203 (3d Cir. 2014) as support for the position that there is no presumption of irreparable harm in Lanham Act cases. Op. at 15 n.3. This was not correct. The Trademark Modernization Act of 2020 amended the Lanham Act to provide that, if a trademark plaintiff demonstrates likelihood of success on the merits, it may be entitled to a *rebuttable* presumption of irreparable harm. 15 U.S.C. § 1116(a); *see Nichino*, 44 F.4th at 185; *Two Hands IP LLC v. Two Hands America, Inc.*, 563 F. Supp. 3d 290, 300 (S.D.N.Y. 2021) (citing 15 U.S.C. § 1116(a)). Thus, Congress effectively overruled *Group SEB* in the 2020 amendment to the Lanham Act.

However, the statute and case law are clear that any presumption of irreparable harm is *rebuttable*, and is rebutted upon a "slight evidentiary showing"

that irreparable harm is unlikely. *Nichino*, 44 F.4th at 186; *see also id.* at 185 n.10 (emphasizing the "small quantum of evidence" necessary); *id.* at 187 ("light burden"). For example, evidence that the consumers at issue are sophisticated and exercise care in purchasing decisions is sufficient to rebut the presumption. *Nichino*, 44 F.4th at 187. Here, likewise, the Court has already found that the relevant consumers are sophisticated healthcare professionals and held that the "consumer care in purchase" *Lapp* factor favors MSN. Op. at 14. That alone is sufficient for MSN to rebut any presumption—even setting aside Novartis's egregious delay and the other evidence discussed below. *See also Equibal, Inc. v. 365 Sun LLC*, 2024 WL 1526178, at *10 (S.D.N.Y. Apr. 9, 2024) (four-month delay between alleged infringer's trademark application and the complaint and another four-month delay between the start of litigation and plaintiffs' motion for a preliminary injunction rebutted presumption); *Two Hands IP LLC*, 563 F. Supp. 3d at 301 (no presumption where plaintiff failed to show likelihood of confusion and plaintiff's three-month delay in seeking injunction).

Second, the Court improperly considered itself bound by "the recognized *theory* of irreparable harm" noted in *Opticians Ass'n of Am. v. Independent Opticians of Am.*, 920 F.2d 187 (3d Cir. 1990). *See* Op. at 17. However, once the presumption has been rebutted, courts cannot rely on an unsupported theory "but instead must rely on *record evidence* demonstrating irreparable harm." *7-Eleven,*

Inc. v. Sodhi, 2016 WL 541135, at *5 (D.N.J. Feb. 9, 2016) (emphasis added) (finding no irreparable harm); *see also Buzz Bee Toys, Inc.*, 20 F. Supp. 3d 511 (finding no irreparable harm and explaining that *Opticians* has been superseded). Just because harm to reputation is one "type of harm that may support temporary injunctive relief . . . does not mean that th[is] harm[] [is] present in the circumstances of this case." *7-Eleven*, 2016 WL 541135, at *5.[1]

By considering itself bound to credit Novartis's "theory of reputational harm" arising from Novartis's purported showing of likely confusion, regardless of the actual factual record in this case, the Court effectively applied an *irrebuttable* presumption of irreparable harm that would apply in any trademark case. That cannot be squared with the Trademark Modernization Act's rebuttable presumption.

b. Novartis Offered Purely Speculative Evidence of Irreparable Harm.

[1] In *Opticians*, the court had before it ample evidence that could reasonably support a showing of irreparable harm. That case involved the defection of a group of optometrists formerly associated with the plaintiff's organization who flagrantly infringed the plaintiff's marks after their membership was terminated and even applied to register the marks in their own name. *See Opticians*, 920 F.2d at 191–92. Similarly, in *AstraZeneca*, the court made the express finding that the defendant was a "second wave generic" with an incentive to be more aggressive to gain market share and intended to create a false association with Plaintiff's mark. *Astrazeneca AB v. Camber Pharms., Inc.*, 2015 WL 7307101, at *4 (D. Del. Nov. 19, 2015).

Under the proper framework set forth in the Trademark Modernization Act and Third Circuit law, Novartis had to offer sufficient proof of irreparable harm through some sort of evidentiary showing to sustain its burden—for example, by offering evidence that MSN's product was lower quality, or that there was actual confusion in the marketplace, or that MSN was attempting in bad faith to create such confusion. Novartis did none of that here. Instead, Novartis offered only a speculative theory of reputational harm was supported by no record evidence and made no sense.

Novartis's primary theory of harm was based on a purported patient safety risk posed by differences between the dosing regimen information on Entresto's and MSN's labels. But MSN has already demonstrated in other litigation that Novartis's "dosage carveout" argument is meritless. In *Novartis Pharmaceuticals Corp. v. Becerra*, 2024 WL 3823270 (D.D.C. Aug. 13, 2024), the court affirmed FDA's well reasoned and thorough rejection of Novartis's argument that the dosing information on MSN's label posed a safety concern. *Id.* at *6. That *Becerra* was not a trademark case is irrelevant.[2] The *factual* theory of harm *Becerra* and the FDA rejected is exactly the same as the one Novartis asserts here, except with another layer of

[2] To the extent Novartis claims that the *Becerra* decision was based on the expedited schedule in that case, that fact does not negate the Court's reasoned rejection Novartis's speculative showing of irreparable harm. *Becerra*, 2024 WL 3823270, at *6. Indeed, MSN is seeking emergency relief here before the Third Circuit so that the period of the stay pending appeal would likely not be more than a few months.

speculation on top—that doctors will be confused about which drug they are prescribing based on the pills' appearance.

Novartis also appears to argue that its reputation will be harmed due to theoretical quality control defects in MSN's drug, but this speculation is even further divorced from the evidentiary record. Novartis offered no support for this theory other than its expert's generalized claims that, because some generic drugs are made in certain countries, they have higher risks of contamination, leading to recalls. *See* ECF 17-1 ("Nayeri Reply Decl.") ¶ 10. But Novartis offered no evidence tying any of this to *MSN* and no evidence of any quality control problem with any MSN product in the history of MSN's existence. Courts now uniformly reject attempts to show irreparable harm through unsubstantiated claims that a defendant's product is inferior. *See Tristar Prods., Inc. v. E. Mishan & Sons, Inc.*, 2017 WL 1404315, at *13–14 (D.N.J. Apr. 19, 2017) ("attorney argument" that infringing product was poor quality and might cause loss of market share insufficient to prove irreparable harm); *Atari Interactive, Inc. v. Printify, Inc.*, 714 F. Supp. 3d 225, 238 (S.D.N.Y. 2024) (a "few conclusory paragraphs" in corporate declaration insufficient to prove inferior quality of defendant's goods); *Kohler Co. v. Bold Int'l FZCO*, 422 F. Supp. 3d 681, 707 (E.D.N.Y. 2018) (rejecting claims of potential damage to plaintiff's goodwill and "high reputation" without evidence that defendant's products were inferior).

But suppose—contrary to all evidence in the record—that Novartis's conjectured quality control incidents come to pass. Then what? The Court's theory is that *doctors*—the relevant consumer here, *see* Op. 14—will blame Entresto because of confusion caused by the pills' physical similarity. How would that work? Following consultation with a patient, a physician writes a prescription for sacubitril/valsartan, typically without even seeing the product because the prescription is filled by the pharmacist. ECF 13-49 ("Ardehali Decl.") ¶ 28. The patient consumes the drug. Days or weeks later, the patient has an adverse reaction and tells his doctor. The doctor checks his chart or notes and sees that generic sacubitril/valsartan was dispensed. In this serious and unusual situation, Novartis's theory is that the doctor will have confused Entresto and one generic product, MSN's, apparently based on the doctor's general awareness—acquired at some unspecified point in the past based on alleged exposure to a Novartis advertisement or to images on Drugs.com—that the drugs look physically similar. And then, Novartis's theory continues, even though the adverse reaction is *the generic's* fault and MSN's brand name and label make no mention of Entresto, this hypothetical doctor will irrationally blame *Novartis* and switch his patients to a generic product or perhaps some completely different drug. Calling this speculative would be an understatement. Further, this Court made clear that the relevant consumers are doctors, not patients, *see* Op. at 14—but even if the relevant consumers were

patients, the Court itself recognized that patients "will be aware of the [generic] substitution." Op. at 10. If patients know they are getting a generic drug, they will not blame Entresto. It is no surprise that *Becerra*, although it did not involve trade dress claims, rejected the precise factual theory of harm Novartis advanced here: "that a brand-name competitor will lose general customer goodwill due to the deficiencies of a generic competitor." *Becerra*, 2024 WL 3823270, at *6. The Court here endorsed the *Becerra* court's conclusion as "well-reasoned." Op. at 17.

Finally, *even if* there were evidence that this remarkably convoluted chain of events would come to pass, Novartis *still* would not be able to show irreparable harm warranting an injunction. Any loss of market share that Novartis experiences, *see* ECF 4-10 ("Robbins Decl.") ¶¶ 18–27, is fully compensable by a damages award. *See Revel AC*, 802 F.3d at 571; *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461, 501 (D.N.J. 2015) ("loss of market share, lost sales, price erosion, and even employee layoffs" as a result of generic entering market are "reducible to a dollar value, and therefore not irreparable" harm).

In sum, the Court was wrong when it held that it was "bound" by trademark law to find irreparable harm. And the Court failed to acknowledge that there was zero evidence supporting Novartis's speculative theory of irreparable harm, a theory the *Becerra* court rejected and this Court found well-reasoned. Further, in analyzing

irreparable harm, the Court failed to address the dispositive point that any loss of market share is compensable.

c. Novartis's Delay Negates Any Claimed Irreparable Harm.

It was also plain error for the Court to find irreparable harm despite Novartis's *years-long delay* in seeking an injunction. Equity "assists the diligent, not the tardy." *Delaware State*, 108 F.4th at 206 (plaintiff's four-month delay weighed against preliminary injunction). The Court expressly found that "Novartis has known about the MSN Drug's purported similar appearance to ENTRESTO for many years" and even tested samples of the drug in 2020. Op. at 16. The Court also acknowledged that "Novartis never raised concerns with the appearance of MSN's pills" and that such facts "would assuredly counsel against a finding of irreparable harm." *Id.* But the Court nonetheless accepted Novartis's razor-thin excuse that its hands were tied because MSN produced the images of its drug and samples under a protective order.

That decision is contrary to law. A protective order does not excuse a party's delay in acting on information produced to it during litigation. In *Cambridge Literary Properties, Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. Kg.*, 448 F. Supp. 2d 244, 264-65 (D. Mass. 2006), *aff'd,* 510 F.3d 77 (1st Cir. 2007), the court refused to toll the statute of limitations when the plaintiff found out about its copyright infringement claim through information produced subject to a protective order. *Id.* The court explained that the plaintiff failed to take any action to change

the confidentiality designation of the relevant documents or to obtain the documents from other sources. *Id.* Here, Novartis's own in-house counsel had access to the images and samples of MSN's pills under the terms of the protective order. *See* ECF 13-9 ("Juang Decl.") ¶¶ 7–10 (identifying Novartis's in-house counsel as a "qualified person"). Novartis explicitly conceded that it reviewed MSN's abbreviated new drug application ("ANDA") and tested MSN's samples. *Id.* & Ex. 6. Yet Novartis took no steps to act on its purported trade dress concerns, such as seeking a carve-out from the protective order or challenging the confidentiality of the images of MSN's pills. Novartis's delay likewise cannot be excused.

Even if Novartis had no duty to take action when it received images of the pills with confidentiality restrictions, it is undisputed that MSN waited *five months* between receiving images of the pills with no confidentiality restrictions and seeking a preliminary injunction. This delay cannot be reconciled with the clear showing of irreparable harm needed for the drastic remedy of an injunction. *See New Dana Perfumes Corp. v. The Disney Store, Inc.*, 131 F. Supp. 2d 616, 630 (M.D. Pa. 2001) (five-month delay in seeking injunctive relief, standing alone, precluded finding of irreparable harm); *Ultimate Trading Corp. v. Daus*, 2007 WL 3025681, at *3 (D.N.J. Oct. 15, 2007) (three-month delay before suing and five-month delay before seeking preliminary injunction negated irreparable harm). Here, as in *Delaware State*, Novartis's delay "suggests that it felt little need to move quickly." 108 F.4th at 206.

The Court's decision to excuse this delay based on the "complexit[y]" of this case, and the fact that MSN's product has not yet launched, was an abuse of discretion unsupported by any legal authority. *See* Op. at 17. Novartis is a highly sophisticated company and has litigated far more complex claims involving MSN's Entresto generic—including an FDA challenge and a multi-district patent litigation against multiple defendants—than the claims presented here, which solely concern the overall look and feel of pills. If it truly feared harm from the appearance of MSN's pills, it was more than capable of sending a cease-and-desist letter or filing a lawsuit months ago. And MSN's ability to launch its product has not changed between August 2024, when Novartis acknowledges it learned of MSN's pill configuration, and a month ago, when Novartis filed this lawsuit seeking "emergency relief" and a temporary restraining order. *See* PI Mot. at 1. In effect, Novartis simply chose to keep its trade dress claim in its back pocket as a last resort if its other attempts to block the release of MSN's product failed. Novartis cannot now claim irreparable harm on such an inequitable record.

2. Novartis Did Not Demonstrate a Likelihood of Success on Its Trade Dress Claim.

a. The Court's Finding of Nonfunctionality Was Based on an Error of Law.

In holding that the Entresto trade dress was nonfunctional, the Court applied an incorrect legal standard that has been expressly rejected by the Third Circuit. To

prove that a trade dress feature is nonfunctional, a plaintiff must show that "*all it does* is identify its maker." *Ezaki Glico Kabushiki Kaisha*, 986 F.3d at 257 (emphasis added). But if the feature does anything more and "gives the product an edge in usefulness," it is functional. *Id.* Crucially, this is true "even when there are alternatives" to the claimed feature. *Id.* at 260. In other words, to be functional, a product feature "need only be useful, not essential." *Id.* at 258.

Here, the Court committed an error of law by applying the incorrect standard *Ezaki Glico* rejected. The Court itself "*credited*" testimony—from Novartis's own expert—that Entresto's appearance "has an element of functionality," because it "serve[s] as [a] useful visual cue[] for patients, particularly more vulnerable populations such as the elderly or others with comorbidities," Op. at 9—the population that takes Entresto. This amounted to a factual finding that the Entresto trade dress is "useful," and thus functional under *Ezaki Glico*. But the Court instead concluded that Novartis's trade dress was nonfunctional because MSN "could have just picked" different colors and shapes. *Id.* That was legal error. As the Third Circuit explained, to be functional, a product feature "need only be useful, not essential." *Ezaki Glico*, 986 F.3d at 258. An efficiency-enhancing product feature is functional "even when there are alternatives." *Id.* at 260.

The Court also erred by not properly applying controlling precedent in *Shire US Inc. v. Barr Lab'ys, Inc.*, 329 F.3d 348 (3d Cir. 2003). The Court distinguished

Entresto from the Adderall at issue in *Shire* because Adderall patients "may take multiple daily dosages of different strengths," and thus "Adderall dosing is more involved." Op. at 9. But the functionality inquiry does not turn on the *degree* of functionality of the claimed feature—again, the feature "need only be useful, not essential." *See Ezaki Glico*, 986 F.3d at 258. Even a simple function, like making a biscuit easy to eat, makes a product feature ineligible for trade dress protection. *See id.* at 259–60. Indeed, the Supreme Court has recognized that the function of a medical pill color may be as simple as "identify[ing] the kind of medicine (*e.g.*, a type of blood medicine)," where (as the Court found here) patients "rely on color to differentiate one [medication] from another." *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 169 (1995).

Here, it is undisputed that Entresto's three pill colors serve to indicate different doses. While Entresto patients may not switch between dosages on a daily basis, Novartis itself explains that they "often" "progress" through the different doses over the course of their treatment, PI Mot. at 6, meaning that they come to associate different pill colors with different doses. Entresto marketing materials also state that patients may sometimes need to lower their dose. ECF 4-59 at 12. Thus, exactly as in *Shire*, "the color coding of a particular [Entresto pill] confers a substantial degree of clinical functionality for the patient in the titration/adjustment process." 329 F.3d at 354. The fact that Entresto dosing may be less "involved"

than Adderall dosing does not mean Entresto's dosage-based color-coding is not useful to patients.

The Court compounded these errors by entirely failing to address the unrebutted evidence that the shape and size of MSN's pills was driven entirely by functional concerns. *See* ECF 13 ("Opp.") at 15–16. An oval shape makes pills easier to swallow, just as the shape of the biscuits in *Ezaki Glico* made them easier to eat. *See* 986 F.3d at 259. And MSN explained the functional reasons why its higher-dose pills are larger than its lower-dose pills. ECF 13-7 ("Nithiyanandam Decl.") ¶ 17. There was *no* evidence to the contrary.

The Court's countervailing policy concern against "expanding" functionality for pill configurations "across every widely available drug" turns the law on its head. *See* Op. at 9. For product design, functionality is the rule, not the exception, because "product design almost invariably serves purposes other than source identification." *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 213 (2000). That is why the burden is on plaintiffs to prove *non*-functionality. That burden exists in all cases—but the case for imposing that burden on plaintiffs is especially strong in the context of prescription generic drugs, where FDA has issued specific guidance that the appearance of the generic drugs should follow the listed drug. ECF 13-46 ("Shimer Decl.") ¶¶ 37–43.

Finally, the Court clearly erred by failing to address key record evidence demonstrating functionality. In assessing the expert testimony, the Court did not cite or address the testimony from Martin Shimer, the former Deputy Director of the FDA's Office of Generic Drugs, explaining that the FDA recommends that generics be similar in size, shape, and appearance to the reference drug for functional reasons. *See generally* Op.; Shimer Decl. ¶¶ 37–43. Mr. Shimer also presented *undisputed* evidence that *every other generic Entresto manufacturer* for whom information is publicly available plans to use a similar color-coding scheme and shape as MSN's product. Opp. at 8 n.4 (citing Nithiyanandam Decl. ¶ 19 & Ex. 1). The fact that other ANDA applications for Entresto adhered to FDA guidance and used the same exact color combinations as MSN, *see* Nithiyanandam Decl. ¶ 18 & Ex. 1; Shimer Decl. ¶¶ 55–56, was strong evidence of functionality not considered by the Court.

The Court's ruling will thus have a dire anticompetitive effect. Every manufacturer that is poised to enter the market for generic Entresto now has a sword hanging over its head: at any point, Novartis might force it to go back to the drawing board and reconfigure its pills in a manner that flouts FDA guidance and risks causing patient confusion and non-adherence—a process that may take months or years to obtain FDA approval of the revised configuration. Effectively, the Court is extending Novartis's monopoly beyond the life of its patents, giving Novartis exclusive control of useful product features and forcing competitors to either use

functionally inferior configurations or leave the market entirely. That is exactly what the functionality doctrine forbids.

b. The Court Erred in Its Analysis of Secondary Meaning.

The Court's ruling on secondary meaning likewise runs afoul of black-letter law. To prove that the Entresto trade dress has secondary meaning, Novartis needed to demonstrate that consumers perceive Entresto's pills' appearance as indicating the *source* of the pills (rather than, for instance, the type of medication). But because "product design almost invariably serves purposes other than source identification," *TrafFix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 29 (2001) (quoting *Wal-Mart*, 529 U.S. at 213), "the proponent of a secondary meaning in product design trade dress faces a formidable burden of proof." 1 McCarthy on Trademarks and Unfair Competition § 8:8.50 (5th ed.). The Court erred in holding that Novartis had met that "formidable" burden. Indeed, all of the relevant factors weigh *against* a finding of secondary meaning here.

No Exclusivity of Use. The Court erred in holding that Novartis's "exclusivity of use" weighed in its favor. Op. at 11. Far from being exclusive to Novartis, there was *unrebutted* evidence of countless other oval-shaped purple, yellow, and pink pills available for sale for various pharmaceutical products. Opp. at 17. The Court also credited MSN's evidence that patients of Entresto include "vulnerable populations such as the elderly or other with comorbidities," Op. at 9,

such that they would be exposed to the hundreds if not thousands of other drugs comprising the claimed trade dress in whole or in part. *See* Opp. at 17 & n.11; Robbins Decl. ¶ 14; ECF 4-11 ("Nayeri Decl.") ¶¶ 49, 60; ECF 13-40 ("Clark Decl.") ¶¶ 75, 81. Even just focusing on medications used for heart failure, the Court overlooked significant third-party use of the claimed trade features, i.e., ovaloid capsules and purple, yellow, and pink colors. *See e.g.*, ECF 13-23 ("Carrero Decl. Ex. 1") at 24, 42, 45, 51, 69, 78, 96, 111, 120, 126, 132, 135, 156, 175, 191, 200, 206, 215, 236, 266; ECF 13-24 ("Carrero Decl. Ex. 2") at 2, 6–7, 12, 15, 18, 81, 85.

The Court discounted or failed to consider this overwhelming evidence of third-party use by improperly defining the relevant market to include only Entresto. Op. at 11 ("ENTRESTO has been the only drug of its kind [sacubitril/valsartan] available to treat patients with heart failure for the last nine years"). In other words, the court was saying, even though doctors can and do prescribe other drugs for heart disease and other illnesses, doctors who prescribe *this specific drug*—sacubitril/valsartan—only had access to Entresto. This was clear error.[3] The relevant "exclusivity" inquiry for purpose of secondary meaning is not confined to

[3] The Court also observed that "color, 'in combination with other characteristics,' can be protectable." Op. at 11 (quoting *Smithkline Beckman Corp. v. Pennex Prods. Co.*, 605 F. Supp. 746, 750 (E.D. Pa. 1985)). Though this may be true in the abstract, that is irrelevant where the Court identified no characteristic of Entresto pills that, in combination with their color, made them distinctive. Indeed, the record showed that each of the Entresto pills' *shape-and-color combinations themselves* are commonly used by third parties.

the market for the precise drug sold by the plaintiff, particularly where, as here, Novartis has enjoyed a monopoly for that drug under now expired or invalid patents. Such an analysis runs afoul of the basic rule that a patent cannot "serve[] as the springboard for converting a legislatively-created [patent] monopoly into a court-enforced permanent [trademark] monopoly." *Zip Dee, Inc. v. Domestic Corp.*, 931 F. Supp. 602, 615 (N.D. Ill. 1996). Under the Court's reasoning, every new patented drug's shape and color, no matter how common, would automatically have secondary meaning—because the manufacturer would have used it "exclusively" in the market its patent allowed it to monopolize. That is not the law.

No Advertising That Calls Attention to Entresto's Appearance as Source-Identifying. The Court's holding that Entresto's marketing materials were probative of secondary meaning was also a legal error. "Secondary meaning cannot be proven by advertising that merely pictures the claimed trade dress and does nothing to emphasize it or call attention to it." 1 McCarthy on Trademarks & Unfair Competition § 8:8.50 (5th ed.); *see, e.g.*, *Forney Indus., Inc. v. Daco of Missouri, Inc.*, 835 F.3d 1238, 1254 (10th Cir. 2016) ("[A]dvertising alone is typically unhelpful to prove secondary meaning when it is not directed at highlighting the trade dress."); *Yankee Candle Co. v. Bridgewater Candle Co.*, 259 F.3d 25, 44 (1st Cir. 2001) (advertising that "[m]erely 'featur[ed]'" relevant trade dress not probative of secondary meaning); *Duraco Prods., Inc. v. Joy Pastic Enters., Ltd.*, 40 F.3d

1431, 1453 (3d Cir. 1994) (advertising did not prove secondary meaning where it did not "emphasize[] [the] alleged trade dress"). Instead, "the advertising must direct the consumer to those features claimed as trade dress." *Buzz Bee Toys*, 20 F. Supp. 3d at 500 (quoting *Yankee Candle*, 259 F.3d at 44).

Entresto marketing materials do not meet this standard. Those materials do nothing to link the pills' appearance to the "Entresto" or "Novartis" brands. They do not tell consumers to look for Entresto's trademark oval-shaped purple, yellow, and pink pills.[4] Nor do they "describe[] [the trade dress] in words," as the Court erroneously found without citing any record evidence. *See* Op. at 12 (quoting *Ciba-Geigy Corp. v. Bolar Pharm. Co.*, 547 F. Supp. 1095, 1101 (D.N.J. 1982)). Instead, each time the materials feature pictures of the Entresto pills, it is to indicate particular *doses*, not a particular *product source*.[5] Thus, as a matter of law, Novartis's marketing materials are *not* probative of secondary meaning, because "[a]dvertising which promotes the functional features of the trade dress fails to promote an association between product and source." McCarthy § 8:8.50 (citing *Devan*

[4] This distinguishes *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Lab'ys*, 532 F. Supp. 1040 (D.N.J. 1980), on which the court relied, *see* Op. at 12, where the plaintiff's advertisements read: "Persantine brand of dipyridamole is available as round orange sugar-coated tablets." *Boehringer*, 532 F. Supp. at 1056.

[5] *See* ECF 4-54; ECF 4-55; ECF 4-58; ECF 4-59 (Bannigan Decl. Exs. 42, 43, 46, 47).

Designs, Inc. v. Palliser Furniture Corp., 1992 WL 511694, at *7 (M.D.N.C. 1992), *aff'd*, 998 F.2d 1008 (4th Cir. 1993)).

Entresto therefore stands in stark contrast to drugs, like AstraZeneca's heartburn medication Nexium or Pfizer's erectile dysfunction drug Viagra, that *are* heavily advertised to emphasize their unique color and/or shape as source-identifying. AstraZeneca associates Nexium with a unique bright purple color by marketing it under the name "the purple pill" and through the website purplepill.com. AstraZeneca has one U.S. trademark registration covering the color purple, two covering a distinctive purple-with-gold-rings pattern, and one covering the tag line "THE PURPLE PILL." *See* U.S. Reg. Nos. 2,806,099, 2,980,749, 3,062,072, and 3,188,285. And Viagra comes in a distinctive diamond-shaped blue tablet, and Pfizer owns a U.S. trademark registration for that unique shape-and-color combination and another for the tag line "LITTLE BLUE PILL." *See* U.S. Reg. Nos. 2,593,407 and 5,214,486.[6]

Novartis, on the other hand, has never promoted the Entresto pills' color-and-shape combinations *as brands* like the "purple pill" or the "little blue pill." Instead,

[6] The Court's policy concern that MSN's "theory" would end trade dress protection for drugs is thus simply wrong. *See* Op. at 11. MSN's position reserves a limited role for trade dress protection for pill configurations that are unique and used as *brands* in marketing materials. Examples like Nexium and Viagra are unusual, but that is simply the consequence of the "formidable burden" of proving secondary meaning in product design. McCarthy § 8:8.50.

Novartis chose to use its three pill colors functionally, to indicate *dosing information.* Significantly, neither Nexium nor Viagra uses dosage-based color-coding to indicate the progression of different dosage levels.

No Evidence That Entresto's Success Was Driven by Its Trade Dress. The Court also erred in relying on Entresto's sales volume as probative of secondary meaning. Sales volume is not evidence of secondary meaning without proof that those sales were generated by the trade dress, rather than "factors other than source identification." *Savant Homes, Inc. v. Collins*, 809 F.3d 1133, 1148 (10th Cir. 2016); *see also Water Pik, Inc. v. Med-Systems, Inc.*, 726 F.3d 1136, 1154–55 (10th Cir. 2013) ("Evidence that its products had millions of users and that its products were sold through well-known retailers does not tell us whether the sales were stimulated by the mark.").

There is no evidence whatsoever that (unlike Nexium and Viagra) *any* of Entresto's sales were driven by its trade dress. Instead, it is obvious that "factors other than source identification" are behind Entresto's success: namely, its clinical effectiveness and Novartis's multi-year monopoly under its patents. The Court's unquestioning reliance on Entresto's sales numbers was thus an error of law.

No Direct Evidence of Secondary Meaning. The Court correctly recognized that Novartis's failure to offer a survey or any consumer testimony weighs heavily against a finding of secondary meaning. *See* Op. at 11–12 (citing *Richardson v.*

Cascade Skating Rink, 2024 WL 3841942, at *8 (D.N.J. Aug. 16, 2024)). That failure is especially glaring given that Entresto has been on the market for years and has been used by millions of patients.

But the Court went astray when it credited the fact testimony of Novartis's expert witness, Dr. Nayeri, that he "recognize[d] Entresto just by seeing the pills." *Id.* at 12 (quoting Nayeri Decl. ¶ 20). First, it is black-letter law that "[t]estimony from a single source" cannot prove secondary meaning. *Art Attacks Ink, LLC v. MGA Ent. Inc.*, 581 F.3d 1138, 1146 (9th Cir. 2009). But the Court's mistake was worse than this, because Dr. Nayeri is not an impartial member of the public—he is being paid $1,300 per hour by Novartis as an expert. Nayeri Decl. ¶ 10. The *ipse-dixit* testimony of a self-interested source is entitled to no weight in proving secondary meaning. *Filipino Yellow Pages, Inc. v. Asian Journal Publ'ns, Inc.*, 198 F.3d 1143, 1152 (9th Cir. 1999) (collecting cases). Crediting this testimony, in the absence of testimony from an unbiased consumer, was legal error.

3. The Balance of Hardships Weighed Against a Preliminary Injunction.

The Court's cursory conclusion that the balance of hardships weighed in favor of Novartis was clearly erroneous. The Court expressly found *actual evidence* of substantial hardship to MSN, recognizing "[t]here is no question that MSN would suffer significant hardship if enjoined," including the loss of its first-mover advantage. Op. at 18. Indeed, the unrebutted evidence shows that Noratech, another

generic Entresto manufacturer, imminently expects FDA approval and will launch its competing Entresto generic as soon as that approval is granted. *See* ECF 13-2 ("Chintapally Decl.") ¶ 32. It is also undisputed that generic drug manufacturers compete based on their ability to consistently and reliably supply customers, and uncertainty about the timing of the release of MSN's product will directly harm its marketplace reputation as a reliable partner. *Id.* ¶¶ 32–34. Moreover, MSN cannot simply change the appearance of its generic without incurring additional, substantial harm. The shape and size of a pill directly affect dissolution and absorption in the body. MSN would have to conduct extensive testing before launching reconfigured pills, which would take two years, if not longer. *Id.* ¶¶ 35–36.

On the other side of the equation, Novartis offered *no evidence* of potential harm at all aside from its legally defective, speculative theory of harm to reputation. *See supra* at 7–17. There was thus clear, unrebutted evidence of irreparable harm to MSN that easily "outweigh[s] the potential harm to Novartis." *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, 2024 WL 3757086, at *5 (D. Del. Aug. 12, 2024).

The Court, however, never engaged in any balancing of the hardships. Instead, relying on *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578, 596 (3d Cir. 2022), it waved away the real and imminent harm to MSN as merely self-inflicted. *See* Op. at 18. Respectfully, this makes no sense in the context of this case. MSN simply did the

same thing as *every other potential entrant in the generic Entresto market*. *See* Nithiyanandam Decl. ¶ 18 & Ex.1. It followed standard industry practice, *see* Clark Decl. ¶¶ 47–61, 87–103, and complied with FDA guidelines recommending that generic drugs resemble their branded counterparts, *see* Shimer Decl. ¶¶ 27–57; Nithiyanandam Decl. ¶¶ 8–14. MSN had no notice that Novartis claimed rights in the Entresto trade dress because, unlike the makers of Nexium and Viagra, Novartis never attempted to obtain a trademark registration. And in any event, MSN took steps to differentiate its product from Entresto by using its own markings and its own, distinctive trademark Novadoz. Nithiyanandam Decl. ¶¶ 15–17. There was not a shred of evidence of bad faith, and indeed, the Court found that MSN did not "necessarily intend[] to create a false impression" about its drug's origin. Op. at 17.

Nor did *Novartis Consumer Health* involve harms as clearly imbalanced as those here. The defendant in that case, "one of the largest companies in America," could avoid harm simply by changing the name and labeling on a single product line, which the court believed it would be able to do "after a short period of time." 290 F.3d at 597 & n.14. But here, as explained above, the harm to MSN is enormous and is not counterbalanced by any potential harm to Novartis.

4. The Court Failed to Properly Weigh the Public Interest Factor.

Finally, the Court clearly erred in its treatment of the public interest factor. The Court made no explicit finding on that factor at all, which alone is legal error.

See Fres-co Sys. USA, Inc. v. Hawkins, 690 F. App'x 72, 80 (3d Cir. 2017) (remanding preliminary injunction order where district court did not properly state its reasons with respect to three of the four factors); *Nichino Am.*, 44 F.4th at 187 ("[A] plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate.").

The Court recognized "the societal benefits of affordable alternatives to brand-name drugs" but identified no countervailing public interest considerations favoring Novartis. Op. at 18. There is no reason this factor should not have weighed in MSN's favor. Indeed, it is beyond dispute that the public has a strong interest in the availability of affordable, lifesaving drugs, and multiple courts have denied preliminary injunctions based on the public interest in increased competition in the marketplace for generic pharmaceuticals. *See Otsuka Pharm.*, 99 F. Supp. 3d at 507; *see also Genentech, Inc. v. Immunex Rhode Island Corp.*, 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019), *aff'd*, 964 F.3d 1109 (Fed. Cir. 2020) (denying preliminary injunction where there was "critical public interest in affordable access to [lifesaving] drugs"); *Warner Lambert Co. v. McCrory's Corp.*, 718 F. Supp. 389, 399 (D.N.J. 1989) (holding in a trademark case that the public interest is best served by allowing defendant to sell its lower priced product pending outcome of the action). And if the injunction stands, the public will be without MSN's generic alternative to Entresto for two years, if not longer—thus increasing the price of

Entresto for consumers solely to avoid a highly speculative theory of physician confusion.

* * *

For these reasons, MSN has easily satisfied its burden to show "a reasonable chance, or probability," of prevailing on its appeal. *Revel AC*, 802 F.3d at 568 (quoting *Singer*, 60 F.3d at 229).

B. MSN Will Suffer Irreparable Harm If a Stay Is Not Granted.

MSN will suffer significant irreparable harm if a stay pending appeal is not granted. As described in Section I.A.3, the Court found *actual evidence* of substantial hardship to MSN. PI Op. at 18. A preliminary injunction causing a delay of even a few weeks in MSN's launch of its product while MSN makes an emergency appeal would likely cost MSN its critical first-mover advantage as the first entrant in the market for generic versions of Entresto. Chintapally Decl. ¶¶ 30–32; Shimer Decl. ¶¶ 58–63. And here, as described above, it will take two years, if not longer, to launch reconfigured pills. Courts have recognized that this precise harm is irreparable warranting denial of injunctive relief. *See In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, 2024 WL 3757086, at *5 ("I am further convinced that MSN's potential harm from the loss of its first-mover advantage would outweigh the potential harm to Novartis."). Further, any delay pending appeal would

irreparably harm MSN's reputation for reliability and impede its ability to negotiate with potential buyers. Chintapally Decl. ¶¶ 33–34.

C. The Balance of the Hardships and the Public Interest Factors Weigh in Favor of a Stay.

For the same reasons addressed in Sections I.A.3 and I.A.4, the balance of the hardships and the public interest factors strongly weigh in favor of a stay pending appeal. Indeed, those factors alone warrant a stay. "Where the balance of harms and public interest 'strongly favor[]' a stay, a court may enter it even if the applicant didn't 'demonstrate as strong a likelihood of ultimate success as would generally be required.'" *Revel AC*, 802 F.3d at 570 (quoting *Delaware River Port Auth. v. Transamerican Trailer Transp., Inc.*, 501 F.2d 917, 923 (3d Cir. 1974)).

* * *

MSN has shown that all four factors weigh in its favor and thus the Court should grant a stay pending appeal. *See Revel AC*, 802 F.3d at 571. However, even if the Court finds that there is a less strong showing of a likelihood of success on the merits of MSN's appeal, it should still stay the injunction given MSN's strong showing of irreparable harm to MSN, the complete lack of evidence of any substantial, non-compensable harm to Novartis, and that the availability of affordable, lifesaving drugs is in the public interest. *See id.* at 570.

II. ALTERNATIVELY, THE COURT SHOULD GRANT MSN A SHORTER STAY TO SEEK RELIEF FROM THE THIRD CIRCUIT.

In the alternative, on the same grounds, MSN requests that at a minimum, enforcement of the injunction be stayed for an amount of time sufficient to permit MSN to seek a stay of the injunction from the Third Circuit Court of Appeals pursuant to Federal Rule of Appellate Procedure 8(a)(2). Specifically, if this Court denies a stay pending appeal, it should nonetheless grant MSN a one-week administrative stay to enable MSN to file a motion for stay in the Third Circuit.[7] If MSN files a motion for stay in that time span, the Court should stay its ruling until the Third Circuit decides MSN's stay motion, or at a minimum, allow a sufficient period of time for the Third Circuit to decide whether to grant its own temporary administrative stay. This modest relief would cause no prejudice to Novartis and would ensure that the Third Circuit is not burdened by emergency filings on a short timespan.

CONCLUSION

For the foregoing reasons, the Court should grant MSN's motion.

[7] MSN reserves all rights to seek a bond pursuant to Federal Rule of Civil Procedure 65(c).

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Respectfully submitted,

/s/ Rebekah Conroy
Rebekah Conroy
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
(973) 400-4181
rconroy@stoneconroy.com

Ron Daignault (admitted *pro hac vice*)
Richard Juang (admitted *pro hac vice*)
DAIGNAULT IYER LLP
8229 Boone Boulevard, Suite 450
Vienna, VA 22182
(917) 838-9795

Gianni P. Servodidio (admitted *pro hac vice*)
Jacquellena T. Carrero (admitted *pro hac vice*)
JENNER & BLOCK LLP
1155 Avenue of the Americas
New York, NY 10036
Tel: (212) 891-1600
Fax: (212) 891-1699
gservodidio@jenner.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of March, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

/s/ Rebekah Conroy
Rebekah Conroy